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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/481,990

Applicant(s)

LESAGE ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,27,28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 7/9/04 has been entered into the record. Claims 11 and 27 were pending. The Amendment added new claim 28. Therefore, claims 11, 27 and 28 are pending and are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The specification is objected to since the middle of page 7 recites that the transmembranal domains are "T1-T4," whereas page 8 and claim 27 recite "M1-M4."

3. Double Patenting

- A. Claims 11 and 27 remain provisionally rejected under US Applications 09/436,265; 09/939,483; 09/939,484; and 09/892,360 as being obvious over one or more claims. Claim 28 is being included in this rejection. Applicants' request that further treatment of the rejection be held in abeyance has been accepted.

4. Claim Rejections - 35 USC § 101

- A. Claim 27 remains rejected and new claim 28 is also rejected under 35 USC 101 for the reasons already of record on pages 2-3 of the Office Action dated 1/6/04. The rejection has been withdrawn for claim 11 largely in view of two of Applicants' arguments – (1) according to pages 9-10 of the specification, that TWIK currents are inhibited by Tedisamile, a Class III antiarrhythmia agent and (2) page 16 of the specification which discloses that TWIK is expressed abundantly in the heart. However, these arguments are only persuasive for the full-length (wild-type) receptor. These arguments are not persuasive for any derivatives of TWIK, thereof. While it is clear that the wild-type TWIK of the invention has a utility in the screening of potential antiarrhythmic agents, this same utility cannot be argued for a "derivative" of the receptor which does not occur naturally. Since these derivatives are not naturally occurring receptors, screening methods, for example, would not be a specific and substantial utility since screening mutated receptors would provide no real-world use. No argument has been made

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by Applicants' regarding TWIK derivatives. Therefore, it is believed that all pertinent arguments have been addressed.

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claim 27 remains rejected and new claim 28 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action dated 1/6/04 as well as for the reasons given in the above rejection under 35 USC 101.

B. Claim 27 remains rejected and new claim 28 is also rejected for the reasons already of record on page 4 of the Office Action dated 1/6/04. Applicants argue that “the specification states on page 13, first and second full paragraphs that SEQ ID NO. 2 can be modified to produce functionally equivalent derivatives, as long as the properties and structure of the TWIK-I channel protein is preserved.” Applicants further argue that these functional limitations are recited in claim 27. Applicants further argue that “the claimed functionally equivalent derivatives must also retain those amino acids which are necessary for retaining the claimed TWIK structure and functionality. One skilled in the art can readily determine which amino acids can and cannot be modified or suppressed by subjecting a putative functionally equivalent derivative to the functional assays outlined on pages 9-12 of the present specification.

These arguments have been considered, but are not deemed persuasive. While it is true that Applicants have recited functional limitations in claim 27, Applicants have not provided and guidance or working examples of which amino acids to alter in order to maintain the functional properties (e.g. potassium flux) of the TWIK protein of SEQ ID NO:2. Respectfully, simply stating that the derivative must have pore domains, transmembrane domains, glycosylation sites and consensus sequences does not provide sufficient guidance to the artisan how to make a functional TWIK protein. For example, Applicants have not taught what residues are critical to maintain the “pore” function of the protein. Furthermore, simply stating that the receptor must have four transmembrane regions does not enable one to make a functional receptor. In other words, it would not be expected that any random amino acids which constitute a transmembrane region would be sufficient to allow functional expression of the “derivative.” In theory, every amino acid in the protein could be altered and would be encompassed by the claims. Therefore, it would not be expected that the artisan could readily determine which amino acids can and cannot be modified without undue experimentation. Again, the standard for enablement is “make

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and use,” not “make and test,” as is apparent from the present disclosure. It is believed that all pertinent arguments have been addressed.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claim 27 remains rejected and new claim 28 is also rejected for the reasons already of record on page 5 of the Office Action dated 1/6/04. Applicants argue that claims 27 and 28 define the claimed functionally equivalent derivatives as being suitable for transporting potassium across a membrane with weak inward rectification as well as having the other recited claim limitations. Hence, claims 27 and 28 are supported by the specification. Therefore, one skilled in the art, given the structural and functional limitations of claims 27 and 28 would recognize that the inventors were in possession of the claimed invention.

7. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 11, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite “an isolated and purified tandem of P domains in a weak inward rectifying potassium channel protein.” However, it is not clear if Applicants are claiming the TWIK protein of SEQ ID NO:2, or if Applicants are only claiming the tandem of P domains from this protein.

8. Conclusion

A. No claim is allowable.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 28, 2004


ROBERT LANDSMAN
PATENT EXAMINER